**IC 12-15-35**

Chapter 35. Drug Utilization Review

**IC 12-15-35-1**

**"Appropriate and medically necessary" defined**

Sec. 1. As used in this chapter, "appropriate and medically necessary" means drug prescribing, drug dispensing, and patient medication usage in conformity with the criteria and standards developed under this chapter.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-2**

**"Board" defined**

Sec. 2. As used in this chapter, "board" refers to the drug utilization review board created under this chapter.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-3**

**"Compendia" defined**

Sec. 3. As used in this chapter, "compendia" means those resources widely accepted by the medical profession in the efficacious use of drugs, including the following sources:

(1) The American Hospital Formulary Services Drug Information.

(2) The U.S. Pharmacopeia-Drug Information.

(3) The American Medical Association Drug Evaluations.

(4) The peer-reviewed medical literature.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-4**

**"Counseling" defined**

Sec. 4. As used in this chapter, "counseling" means the activities conducted by a pharmacist to inform Medicaid recipients about the proper use of drugs as required by the board under this chapter.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-4.5**

**"Covered outpatient drug" defined**

Sec. 4.5. As used in this chapter, "covered outpatient drug" has the meaning set forth in 42 U.S.C. 1396r-8(k)(2).

*As added by P.L.107-2002, SEC.12.*

**IC 12-15-35-5**

**"Criteria" defined**

Sec. 5. As used in this chapter, "criteria" means the predetermined and explicitly accepted elements that are used to measure drug use on an ongoing basis to determine if the use is appropriate, medically necessary, and not likely to result in adverse medical outcomes.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-6**

**"Drug-disease contraindication" defined**

Sec. 6. As used in this chapter, "drug-disease contraindication" means an occurrence in which the therapeutic effect of a drug is adversely altered by the presence of another disease condition.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-7**

**"Drug-drug interaction" defined**

Sec. 7. As used in this chapter, "drug-drug interaction" means an occurrence in which at least two (2) drugs taken by a recipient leads to clinically significant toxicity that:

(1) is characteristic of one (1) or any of the drugs present; or

(2) leads to the interference with the effectiveness of one (1) or any of the drugs.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-8**

**"Drug utilization review" or "DUR" defined**

Sec. 8. As used in this chapter, "drug utilization review" or "DUR" means the program designed to measure and assess on a retrospective and a prospective basis the proper use of outpatient drugs in the Medicaid program.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-9**

**"Intervention" defined**

Sec. 9. As used in this chapter, "intervention" means an action taken by the board with a prescriber or pharmacist to inform about or to influence prescribing or dispensing practices or utilization of drugs.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-10**

**"Overutilization or underutilization" defined**

Sec. 10. As used in this chapter, "overutilization or underutilization" means the use of a drug in such quantities where the desired therapeutic goal is not achieved.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-11**

**"Pharmacist" defined**

Sec. 11. As used in this chapter, "pharmacist" means an individual who is licensed as a pharmacist in Indiana under IC 25-26.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-12**

**"Physician" defined**

Sec. 12. As used in this chapter, "physician" means an individual who is licensed to practice medicine in Indiana under IC 25-22.5.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-13**

**"Prospective DUR" defined**

Sec. 13. As used in this chapter, "prospective DUR" means the part of the drug utilization review program that:

(1) is to occur before the drug is dispensed;

(2) is designed to screen for potential drug therapy problems based on explicit and predetermined criteria and standards that are developed on an ongoing basis with professional input; and

(3) is to provide for the counseling of recipients about the proper use of drugs.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-14**

**"Retrospective DUR" defined**

Sec. 14. As used in this chapter, "retrospective DUR" means the part of the drug utilization review program that assesses or measures drug use based on an historical review of drug use data against predetermined and explicit criteria and standards that are developed on an ongoing basis with professional input.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-15**

**"Standards" defined**

Sec. 15. As used in this chapter, "standards" means the acceptable range of deviation from the criteria that reflects local medical practice and that is tested on the Medicaid recipient database.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-16**

**"SURS" defined**

Sec. 16. As used in this chapter, "SURS" refers to the surveillance utilization review system of the Medicaid program.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-17**

**"Therapeutic appropriateness" defined**

Sec. 17. As used in this chapter, "therapeutic appropriateness" means drug prescribing based on rational drug therapy that is consistent with the criteria and standards developed under this chapter.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-17.5**

**"Therapeutic classification" or "therapeutic category" defined**

Sec. 17.5. As used in this chapter, "therapeutic classification" or "therapeutic category" means a group of pharmacologic agents primarily characterized by a significant similarity of the biochemical or physiological mechanism by which these agents result in the

intended clinical outcome.
*As added by P.L.107-2002, SEC.13.*

**IC 12-15-35-18**
**"Therapeutic duplication" defined**

Sec. 18. As used in this chapter, "therapeutic duplication" means the prescribing and dispensing of:

(1) the same drug; or

(2) at least two (2) drugs from the same therapeutic class;

where overlapping periods of drug administration are involved and where such prescribing or dispensing is not medically indicated.
*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-18.5**
**Application of chapter**

Sec. 18.5. This chapter applies to any contractor or vendor of the state responsible for providing or managing any part of the Medicaid outpatient drug program.
*As added by P.L.76-1994, SEC.2.*

**IC 12-15-35-18.7**
**Formulary requirements**

Sec. 18.7. A formulary established by a Medicaid managed care organization is subject to sections 46 and 47 of this chapter.
*As added by P.L.231-1999, SEC.2.*

**IC 12-15-35-19**
**Drug utilization review board; establishment**

Sec. 19. The drug utilization review board is established.
*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-20**
**Membership of board**

Sec. 20. The board is composed of the following:

(1) Four (4) individuals licensed and actively engaged in the practice of medicine or osteopathic medicine in Indiana under IC 25-22.5.

(2) Four (4) individuals licensed under IC 25-26 and actively engaged in the practice of pharmacy in Indiana.

(3) One (1) individual with expertise in therapeutic pharmacology who is neither a physician or a pharmacist.

(4) A representative of the office who shall serve as an ex-officio nonvoting member of the board.

(5) One (1) individual who:

(A) is employed by a health maintenance organization that has a pharmacy benefit; and

(B) has expertise in formulary development and pharmacy benefit administration.

The individual appointed under this subdivision may not be employed by a health maintenance organization that is under

contract or subcontract with the state to provide services to Medicaid recipients under this article.

(6) One (1) individual who is a health economist.

*As added by P.L.75-1992, SEC.19. Amended by P.L.231-1999, SEC.3.*

**IC 12-15-35-20.1**

**Conflicts of interest**

Sec. 20.1. (a) Each board member and each therapeutics committee member shall fully disclose any potential conflicts of interest, financial or otherwise, relating to an issue that comes before the board or committee for recommendation or other action.

(b) A board member or therapeutics committee member may not vote on a recommendation or other action if the member or the member's employer has a conflict of interest, financial or otherwise, in the outcome of the vote.

(c) A board member or therapeutics committee member who may not vote on a recommendation or other action under subsection (b) may still participate in any discussions regarding the recommendation or other action.

*As added by P.L.231-1999, SEC.4. Amended by P.L.107-2002, SEC.14.*

**IC 12-15-35-20.5**

**Therapeutics committee established; members; limitations; terms; votes; meetings**

Sec. 20.5. (a) The therapeutics committee is established as a subcommittee of the board.

(b) The chairperson of the board elected under section 25 of this chapter shall, with the approval of a majority of a quorum of the board, appoint the members of the therapeutics committee.

(c) The therapeutics committee is composed of the following members:

(1) Five (5) physicians licensed under IC 25-22.5, including:

(A) one (1) physician with expertise in the area of family practice;

(B) one (1) physician with expertise in the area of pediatrics;

(C) one (1) physician with expertise in the area of geriatrics;

(D) one (1) physician with expertise in psychiatric medicine; and

(E) one (1) physician with expertise in the area of internal medicine and who specializes in the treatment of diabetes.

(2) Two (2) pharmacists who are licensed under IC 25-26 and who have a doctor of pharmacy degree or an equivalent degree.

(d) Not more than three (3) of the individuals appointed by the chairperson under subsection (b) to the therapeutics committee may also be members of the board.

(e) At least three (3) of the members described in subsection (c)(1) and appointed under subsection (b) must have at least three (3) years of recent experience in prescription drug formulary

management, including therapeutic category review.

(f) A member of the therapeutics committee may not:

(1) be employed by; or

(2) contract with;

the state or a pharmaceutical manufacturer or labeler. However, this subsection does not apply to a physician or a pharmacist whose only contract with the state is a Medicaid provider agreement under IC 12-15-11 or a provider agreement under the children's health insurance program under IC 12-17.6.

(g) The term of a member of the therapeutics committee is three (3) years. A member may be reappointed to the committee upon the completion of the member's term.

(h) The expenses of the therapeutics committee shall be paid by the office.

(i) Each member of the therapeutics committee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). The member is also entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(j) The affirmative votes of a majority of a quorum of the therapeutics committee are required for the committee to take action on any measure. A quorum of the therapeutics committee consists of four (4) members.

(k) The therapeutics committee shall meet:

(1) upon the call of the chairperson of the therapeutics committee; and

(2) at least quarterly.

(l) The chairperson and the vice chairperson of the therapeutics committee:

(1) each serve for a term of one (1) year; and

(2) must be elected from the therapeutics committee's membership at the therapeutics committee's first meeting each calendar year.

(m) A meeting held by the therapeutics committee must be open to the public in accordance with IC 5-14-1.5. However, the therapeutics committee may meet in executive session only for the purpose of reviewing confidential or proprietary information.

*As added by P.L.107-2002, SEC.15.*

**IC 12-15-35-21**

**Board; appointment; term**

Sec. 21. (a) The members of the board shall be appointed by the governor and serve a term of three (3) years.

(b) The governor shall fill a vacancy on the board by appointing a new member to serve the remainder of the unexpired term.

(c) The governor may remove a member for cause.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-22**

**Qualifications of board members**

Sec. 22. Board members must have expertise in one (1) or more of the following:

(1) Clinically appropriate prescribing of outpatient drugs.

(2) Clinically appropriate dispensing and monitoring of outpatient drugs.

(3) Drug utilization review, evaluation, and intervention.

(4) Medical quality assurance.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-23**

**Physician appointments; geographic balance**

Sec. 23. In making the physician appointments, the governor shall provide for geographic balance.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-24**

**Reappointment of members**

Sec. 24. An individual appointed to the board may be reappointed upon the completion of the individual's term.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-25**

**Chairman; compensation; expenses**

Sec. 25. (a) The board shall annually elect a chairman from the members of the board.

(b) The chairman may be re-elected to serve consecutive terms as chairman.

(c) A member of the board who is not a state employee is entitled to the minimum salary per diem as provided by IC 4-10-11-2.1(b). Each member of the board is entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties as provided in the state travel policies and procedures established by the Indiana department of administration and the budget agency.

(d) Each member of the board who is a state employee is entitled to reimbursement for traveling expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the Indiana department of administration and approved by the budget agency.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-26**

**Additional staff**

Sec. 26. (a) The secretary shall provide additional staff to the board.

(b) The secretary shall provide staff for the therapeutics committee.

*As added by P.L.75-1992, SEC.19. Amended by P.L.291-2001,*

*SEC.162; P.L.107-2002, SEC.16.*

**IC 12-15-35-27**

**Retrospective and prospective DUR program responsibility**

Sec. 27. The board is responsible for the oversight of the retrospective and prospective DUR program.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-28 Version a**

**Duties of board**

*Note: This version of section effective until 7-1-2005. See also following version of this section, effective 7-1-2005.*

Sec. 28. (a) The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year. The report issued to the legislative council must be in an electronic format under IC 5-14-6.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational

information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for:

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program; and

(C) the primary care case management component of the children's health insurance program under IC 12-17.6;

in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(15) Advising the Indiana comprehensive health insurance association established by IC 27-8-10-2.1 concerning implementation of chronic disease management and pharmaceutical management programs under IC 27-8-10-3.5.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under

subsection (a)(11), the board shall do the following:

(1) Use literature abstracting technology.

(2) Use commonly accepted guidance principles of disease management.

(3) Develop therapeutic classifications for the preferred drug list.

(4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that is not included on the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date on which the manufacturer notifies the board in writing of the drug's approval. However, if the board determines that there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be automatically required for a single source drug that is newly approved by the federal Food and Drug Administration, and that is:

(1) in a therapeutic classification:

(A) that has not been reviewed by the board; and

(B) for which prior authorization is not required; or

(2) the sole drug in a new therapeutic classification that has not been reviewed by the board.

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list developed under subsection (a)(11):

(1) Except as provided by IC 12-15-35.5-3(b) and IC 12-15-35.5-3(c), the office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

(A) To override a prospective drug utilization review alert.

(B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.

(C) To prevent fraud, abuse, waste, overutilization, or inappropriate utilization.

(D) To permit implementation of a disease management program.

(E) To implement other initiatives permitted by state or federal law.

(2) All drugs described in IC 12-15-35.5-3(b) must be included on the preferred drug list.

(3) The office may add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list without prior approval from the board.

(4) The board may add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list.

(h) At least two (2) times each year, the board shall provide a report to the select joint commission on Medicaid oversight established by IC 2-5-26-3. The report must contain the following information:

(1) The cost of administering the preferred drug list.

(2) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.

(3) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.

(4) The number of times prior authorization was requested, and the number of times prior authorization was:

(A) approved; and

(B) disapproved.

(i) The board shall provide the first report required under subsection (h) not later than six (6) months after the board submits an initial preferred drug list to the office.

*As added by P.L.75-1992, SEC.19. Amended by P.L.76-1994, SEC.3; P.L.107-2002, SEC.17; P.L.184-2003, SEC.7; P.L.193-2003, SEC.2; P.L.28-2004, SEC.104; P.L.97-2004, SEC.51; P.L.2-2005, SEC.50.*

**IC 12-15-35-28 Version b**

**Duties of board**

*Note: This version of section effective 7-1-2005. See also preceding version of this section, effective until 7-1-2005.*

Sec. 28. (a) The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the

compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year. The report issued to the legislative council must be in an electronic format under IC 5-14-6.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3.1 and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for:

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program;

(C) Medicaid's risk based managed care program, if the office provides a prescription drug benefit and subject to IC 12-15-5; and

(D) the children's health insurance program under IC 12-17.6;

in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(15) Advising the Indiana comprehensive health insurance association established by IC 27-8-10-2.1 concerning implementation of chronic disease management and pharmaceutical management programs under IC 27-8-10-3.5.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

(1) Use literature abstracting technology.

(2) Use commonly accepted guidance principles of disease management.

(3) Develop therapeutic classifications for the preferred drug list.

(4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that is not included on the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date on which the manufacturer notifies the board in writing of the drug's approval. However, if the board determines that there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be automatically required for a single source drug that is newly approved by the federal Food and Drug Administration, and that is:

(1) in a therapeutic classification:

(A) that has not been reviewed by the board; and

(B) for which prior authorization is not required; or

(2) the sole drug in a new therapeutic classification that has not been reviewed by the board.

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list developed under subsection (a)(11):

(1) Except as provided by IC 12-15-35.5-3(b) and IC 12-15-35.5-3(c), the office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

(A) To override a prospective drug utilization review alert.

(B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.

(C) To prevent fraud, abuse, waste, overutilization, or inappropriate utilization.

(D) To permit implementation of a disease management program.

(E) To implement other initiatives permitted by state or federal law.

(2) All drugs described in IC 12-15-35.5-3(b) must be included on the preferred drug list.

(3) The office may add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list without prior approval from the board.

(4) The board may add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list.

(h) At least two (2) times each year, the board shall provide a report to the select joint commission on Medicaid oversight established by IC 2-5-26-3. The report must contain the following information:

(1) The cost of administering the preferred drug list.

(2) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.

(3) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.

(4) The number of times prior authorization was requested, and the number of times prior authorization was:

(A) approved; and

(B) disapproved.

(i) The board shall provide the first report required under subsection (h) not later than six (6) months after the board submits an initial preferred drug list to the office.

*As added by P.L.75-1992, SEC.19. Amended by P.L.76-1994, SEC.3; P.L.107-2002, SEC.17; P.L.184-2003, SEC.7; P.L.193-2003, SEC.2; P.L.28-2004, SEC.104; P.L.97-2004, SEC.51; P.L.2-2005, SEC.50;*

*P.L.101-2005, SEC.3.*

**IC 12-15-35-28.5**

**Therapeutics committee duties**

Sec. 28.5. The therapeutics committee established under section 20.5 of this chapter shall do the following:

(1) Advise and make recommendations to the board in the board's development and maintenance of a preferred drug list under section 28 of this chapter.

(2) Submit to the board a proposed preferred drug list that has been approved by a majority of a quorum of the therapeutics committee.

(3) Advise and make recommendations to the board in the board's review and maintenance of a preferred drug list.

*As added by P.L.107-2002, SEC.18.*

**IC 12-15-35-28.7**

**Submitting initial preferred drug list; limitations on restrictions; advance notice to providers; implementation; prior authorization limitation; rules**

Sec. 28.7. (a) The board shall submit the initial approved preferred drug list to the office not later than August 1, 2002.

(b) Except as permitted under subsection (g), the office may not further restrict the status of a drug in the Medicaid program or the children's health insurance program until the board reviews a therapeutic classification and the office implements the therapeutic classification on the preferred drug list.

(c) The office shall provide advance notice to providers of the contents of the preferred drug list submitted by the board under subsection (a).

(d) Notwithstanding IC 12-15-13-6, the office shall implement any change in the preferred drug list not later than thirty (30) days after the date the board submits the amended list to the office.

(e) Except as provided by section 28(g)(3) of this chapter, the office may not implement a preferred drug list or an amendment to the preferred drug list that has not been approved by the board.

(f) The office may not require prior authorization for a drug that is excluded from the preferred drug list unless the board has made the determinations required under section 35 of this chapter.

(g) The office may adopt rules under IC 4-22-2 necessary to carry out this chapter.

*As added by P.L.107-2002, SEC.19. Amended by P.L.184-2003, SEC.8.*

**IC 12-15-35-29**

**Quorum; majority vote on DUR criteria and standards for prescribing**

Sec. 29. (a) A quorum consists of six (6) voting members of the board.

(b) DUR criteria and standards for appropriate prescribing may

only be implemented with the approval of a majority of the quorum of the board. The majority vote must include at least three (3) of the four (4) physician members of the board and may allow the board to accept deviations from the standards on a case-by-case basis.
*As added by P.L.75-1992, SEC.19. Amended by P.L.231-1999, SEC.5.*

**IC 12-15-35-30**
**Local practices; monitoring**

Sec. 30. The criteria and standards developed under section 28(3) of this chapter for appropriate prescribing that are implemented must reflect the local practices of physicians to monitor the following:

(1) Therapeutic appropriateness.
(2) Overutilization or underutilization.
(3) Therapeutic duplication.
(4) Drug-disease contraindications.
(5) Drug-drug interactions.
(6) Incorrect drug dosage or duration of drug treatment.
(7) Clinical abuse and misuse.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-31**
**Intervention; approval; requisites**

Sec. 31. (a) An intervention developed under section 28(4) of this chapter that involves a physician must be approved by at least three (3) of the four (4) physician members of the board before implementation.

(b) An intervention that involves a pharmacist must be approved by at least three (3) of the four (4) pharmacist members of the board before implementation.

(c) Interventions include the following:

(1) Information disseminated to physicians and pharmacists to ensure that physicians and pharmacists are aware of the board's duties and powers.
(2) Written, oral, or electronic reminders of recipient-specific or drug-specific information that are designed to ensure recipient, physician, and pharmacist confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care.
(3) Use of face-to-face discussions between experts in drug therapy and the prescriber or pharmacist who has been targeted for educational intervention.
(4) Intensified reviews or monitoring of selected prescribers or pharmacists.
(5) The creation of an educational program using data provided through DUR to provide for active and ongoing educational outreach programs to improve prescribing and dispensing practices.
(6) The timely evaluation of interventions to determine if the interventions have improved the quality of care.

(7) The review of case profiles before the conducting of an intervention.

*As added by P.L.75-1992, SEC.19.*

Repealed

(*Repealed by P.L.76-1994, SEC.7.)*

**IC 12-15-35-32.1**

**Annual report contents**

Sec. 32.1. The annual report under section 28 of this chapter shall include information on the following:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use and any changes in criteria.

(4) A description of the nature and scope of the retrospective DUR program.

(5) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(6) An estimate of the cost savings generated as a result of the DUR program including savings to the Medicaid drug program attributable to the prospective and retrospective DUR.

(7) An overview of the fiscal impact of the DUR program on other areas of the Medicaid program.

(8) A quantifiable assessment of how DUR has improved quality of care.

(9) A summary of the total number of prescriptions reviewed by drug therapeutic class.

*As added by P.L.76-1994, SEC.4.*

**IC 12-15-35-33**

**Repealed**

(*Repealed by P.L.1-1993, SEC.132.)*

**IC 12-15-35-34**

**Confidential identifying information; release of cumulative nonidentifying information**

Sec. 34. (a) Information that identifies an individual collected under this chapter is confidential and may not be disclosed by the board.

(b) The board may have access to identifying information for purposes of carrying out intervention activities. The identifying information may not be released to anyone other than a member of the board.

(c) The board may release cumulative non-identifying information for purposes of legitimate research.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-35**

**Prior approval program for outpatient drugs; standards**

Sec. 35. (a) Before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least fifteen (15) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least fifteen (15) days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(b) The board shall advise the office on the implementation of any

program to restrict the use of brand name multisource drugs.

(c) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

*As added by P.L.75-1992, SEC.19. Amended by P.L.76-1994, SEC.5; P.L.231-1999, SEC.6; P.L.6-2002, SEC.3; P.L.107-2002, SEC.20; P.L.1-2003, SEC.58.*

**IC 12-15-35-36**

**Advisory committees**

Sec. 36. The board may establish advisory committees to assist the board in carrying out the board's duties under this chapter.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-37**

**Medicaid state plan; inclusion of retrospective and prospective DUR program**

Sec. 37. The board shall, in cooperation with the secretary, include in the Medicaid state plan the creation and implementation of a retrospective and prospective DUR program for Medicaid outpatient drugs to ensure that the prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-38**

**DUR program guidelines and procedures**

Sec. 38. The retrospective and prospective DUR program shall be operated under the guidelines and procedures established by the board under section 29 of this chapter.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-39**

**Retrospective DUR requisites**

Sec. 39. Retrospective DUR must:

(1) be based on the guidelines established by the board; and

(2) use the mechanized drug claims processing and information retrieval system to analyze claims data to do the following:

(A) Identify patterns of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care.

(B) Assess data on drug use against explicit predetermined standards that are based on the compendia and other sources to monitor the following:

(i) Therapeutic appropriateness.

(ii) Overutilization or underutilization.

(iii) Therapeutic duplication.

(iv) Drug-disease contraindications.

(v) Drug-drug interactions.

(vi) Incorrect drug dosage or duration of drug treatment.

(vii) Clinical abuse and misuse.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-40**

**Prospective DUR requisites**

Sec. 40. Prospective DUR must be based on the guidelines established by the board and must provide that prior to the prescription being filled or delivered a review will be conducted by the pharmacist at the point of sale to screen for potential drug therapy problems resulting from the following:

(1) Therapeutic duplication.

(2) Drug-drug interactions.

(3) Incorrect dosage and duration of treatment.

(4) Drug-allergy interactions.

(5) Clinical abuse and misuse.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-41**

**Board activities under IC 34-30-15**

Sec. 41. The activities of the board in carrying out this chapter are covered under IC 34-30-15.

*As added by P.L.75-1992, SEC.19. Amended by P.L.1-1998, SEC.103.*

**IC 12-15-35-42**

**Meetings**

Sec. 42. (a) The board may meet in an executive session for purposes of reviewing DUR data or to conduct or to discuss activity as provided for in IC 5-14-1.5-6.1.

(b) The board shall also conduct regular public meetings to gather input from the public on the operation of the DUR program.

(c) The board shall meet monthly to implement its duties under this chapter.

*As added by P.L.75-1992, SEC.19. Amended by P.L.291-2001, SEC.163.*

**IC 12-15-35-43**

**Confidentiality; pharmacist data and information**

Sec. 43. Confidential data or information obtained by pharmacists as part of prospective DUR are confidential but may be released to prescribers or others according to procedures established by the board.

*As added by P.L.75-1992, SEC.19.*

**IC 12-15-35-43.5**

**Prohibiting the release of proprietary or confidential information obtained under certain circumstances**

Sec. 43.5. (a) The board, the therapeutics committee, or the office may not release proprietary or confidential information obtained as

part of the development, implementation, or maintenance of a preferred drug list under this chapter.

(b) Information described in subsection (a) is confidential for purposes of IC 5-14-3-4(a)(1).

*As added by P.L.107-2002, SEC.21. Amended by P.L.184-2003, SEC.9.*

**IC 12-15-35-44**

**Confidentiality; violations; penalty**

Sec. 44. A person who does not comply with the confidentiality provisions under section 34 of this chapter commits a Class A misdemeanor.

*As added by P.L.75-1992, SEC.19. Amended by P.L.1-1993, SEC.133.*

**IC 12-15-35-45**

**Outpatient drug formulary; requirements**

Sec. 45. (a) The chairman of the board, subject to the approval of the board members, may appoint an advisory committee to make recommendations to the board on the development of a Medicaid outpatient drug formulary.

(b) If the office decides to establish a Medicaid outpatient drug formulary, the formulary shall be developed by the board.

(c) A formulary, preferred drug list, or prescription drug benefit used by a Medicaid managed care organization is subject to IC 12-15-5-5, IC 12-15-35.5, and sections 46 and 47 of this chapter.

*As added by P.L.76-1994, SEC.6. Amended by P.L.231-1999, SEC.7; P.L.101-2005, SEC.4.*

**IC 12-15-35-46**

**Review of proposed formulary**

Sec. 46. (a) This section applies to a managed care organization that enters into an initial contract with the office to be a Medicaid managed care organization after May 13, 1999.

(b) Before a Medicaid managed care organization described in subsection (a) implements a formulary, the managed care organization shall submit the formulary to the office at least thirty-five (35) days before the date that the managed care organization implements the formulary for Medicaid recipients.

(c) The office shall forward the formulary to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will review a Medicaid managed care organization's proposed formulary at a particular board meeting. The notification shall contain the following information:

(1) A statement of the date, time, and place at which the board meeting will be convened.

(2) A general description of the subject matter of the board meeting.

(3) An explanation of how a copy of the formulary to be

discussed may be obtained.

The board shall meet to review the formulary at least thirty (30) days but not more than sixty (60) days after the notification.

(e) In reviewing the formulary, the board shall do the following:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that the use of the formulary will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Make a determination that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary;

(B) a process is in place through which a Medicaid member has access to medically necessary drugs; and

(C) the managed care organization otherwise meets the requirements of IC 27-13-38.

(f) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendation to the office.

(g) Within thirty (30) days after the board meeting, the board shall make a recommendation to the office regarding whether the proposed formulary should be approved, disapproved, or modified.

(h) The office shall rely significantly on the clinical expertise of the board. If the office does not agree with the recommendations of the board, the office shall, at a public meeting, discuss the disagreement with the board and present any additional information to the board for the board's consideration. The board's consideration of additional information must be conducted at a public meeting.

(i) Based on the final recommendations of the board, the office shall approve, disapprove, or require modifications to the Medicaid managed care organization's proposed formulary. The office shall notify the managed care organization of the office's decision within fifteen (15) days of receiving the board's final recommendation.

(j) The managed care organization must comply with the office's decision within sixty (60) days after receiving notice of the office's decision.

(k) Notwithstanding the other provisions of this section, the office may temporarily approve a Medicaid managed care organization's proposed formulary pending a final recommendation from the board.

*As added by P.L.231-1999, SEC.8.*

**IC 12-15-35-47**

**Review of changes to formulary**

Sec. 47. (a) This section applies to the following changes to a formulary used by a Medicaid managed care organization for

Medicaid recipients:

(1) Removing one (1) or more drugs from the formulary.

(2) Placing new restrictions on one (1) or more drugs on the formulary.

(b) Before a Medicaid managed care organization makes a change described in subsection (a), the managed care organization shall submit the proposed change to the office.

(c) The office shall forward the proposed change to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will:

(1) review the proposed change; and

(2) consider evidence and credible information provided to the board;

at the board's regular board meeting before making a recommendation to the office regarding whether the proposed change should be approved or disapproved.

(e) Based on the final recommendation of the board, the office may approve or disapprove the proposed change. If a proposed change is not disapproved within ninety (90) days after the date the managed care organization submits the proposed change to the office, the managed care organization may implement the change to the formulary.

(f) A Medicaid managed care organization:

(1) may add a drug to the managed care organization's formulary without the approval of the office; and

(2) shall notify the office of any addition to the managed care organization's formulary within thirty (30) days after making the addition.

*As added by P.L.231-1999, SEC.9.*

**IC 12-15-35-48**

**Board's review of a managed care organization's prescription drug program; report**

Sec. 48. (a) The board shall review the prescription drug program of a managed care organization that participates in the state's risk-based managed care program at least one (1) time per year. The board's review of a prescription drug program must include the following:

(1) An analysis of the single source drugs requiring prior authorization, including the number of drugs requiring prior authorization in comparison to other managed care organizations' prescription drug programs that participate in the state's Medicaid program.

(2) A determination and analysis of the number and the type of drugs subject to a restriction.

(3) A review of the rationale for:

(A) the prior authorization of a drug described in subdivision (1); and

(B) a restriction on a drug.

(4) A review of the number of requests a managed care organization received for prior authorization, including the number of times prior authorization was approved and the number of times prior authorization was disapproved.

(5) A review of:

(A) patient and provider satisfaction survey reports; and

(B) pharmacy-related grievance data for a twelve (12) month period.

(b) A managed care organization described in subsection (a) shall provide the board with the information necessary for the board to conduct its review under subsection (a).

(c) The board shall report to the select joint commission on Medicaid oversight established by IC 2-5-26-3 at least one (1) time per year on the board's review under subsection (a).

*As added by P.L.107-2002, SEC.22.*

**IC 12-15-35-49**

**Information provided by office**

Sec. 49. (a) The office shall provide the board with information necessary for the board to carry out its duties under this chapter.

(b) The office shall provide the information required under subsection (a):

(1) when requested by the board; and

(2) in a timely manner.

*As added by P.L.291-2001, SEC.164.*